White Paper

# American Health Information Community Successor

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#### Introduction

This white paper describes the vision for and attributes of a successor to the American Health Information Community (AHIC). Specifically, it describes the purpose and scope of a successor entity, presents governance and operating objectives, and highlights several legal considerations associated with the formation of the AHIC successor.<sup>2</sup>

The AHIC seeks public comment on the contents of this white paper. Specific instructions for providing comments are available on the AHIC successor web page:

http://www.hhs.gov/healthit/community/background/AHICsuccessor.html.

#### American Health Information Community

The American Health Information Community (AHIC) is a federal advisory body chartered in 2005 to make recommendations to the Secretary of the U.S. Department of Health and Human Services (HHS) on how to accelerate the development and adoption of health information technology. The advisory nature of AHIC and its Workgroups has been invaluable in creating a forum to seek input and guidance to understand key issues and policy implications necessary to achieve President Bush's goal for most Americans to have access to secure electronic health records by 2014.

The AHIC charter requires responsibilities to be transferred to a successor. Therefore, the AHIC is embarking upon a project that will take the Community to the next level. The AHIC successor will be an independent and sustainable public-private partnership bringing together the best attributes and resources of public and private entities. This new public-private partnership will develop a unified approach to realize an effective, interoperable nationwide health information system¹ that supports the health and well-being of individuals and communities in the U.S.

Recognizing that interoperability is critical to realizing both improvements in quality and efficiency in the U.S. health system, and understanding the importance of continuity of leadership to maintaining the AHIC's momentum toward achieving interoperability, the Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC) will engage with the private sector to seamlessly transition the locus of activity from a Federal advisory committee to an independent public-private partnership that is focused on achieving interoperability across the health care system.

Between now and the Spring of 2008, AHIC members and AHIC Workgroups will continue efforts to identify obstacles to the adoption of interoperable health information technology (IT) and make specific recommendations to the Secretary of (HHS). At the same time, HHS has embarked upon an effort that will take AHIC to the next level by facilitating the development of an independent public-private partnership that is results-oriented, inclusive, and coordinated with quality and transparency initiatives. The new entity will build on the AHIC achievements and will require exceptional leadership as well as a broad base of both public and private support to realize the vision of an interoperable health care system.

<sup>&</sup>lt;sup>2</sup> **Disclamer:** This document is intended to provide general information to assist in discussions regarding an AHIC successor entity. The document may contain general legal information and should not be construed as legal advice to be applied to any factual situation. HHS makes no claims, promises, or guarantees about the accuracy, completeness, or adequacy of the information contained in this white paper.



<sup>&</sup>lt;sup>1</sup> The nationwide health information system refers to the National Health Information Network (NHIN), certified Electronic Health Records (EHRs) used across settings of care, personal health records, public health and other data intermediaries that enable health information exchange across health care and public health entities.

The AHIC successor will bring together both public and private, not-for-profit and for-profit entities that represent all sectors of the health community. It is essential that the Federal government play a substantial role in order to accelerate the emergence of an interoperable nationwide health information system. Designing and establishing an AHIC successor is neither an effort to privatize the role of AHIC, nor is it Federal Government preemption. Instead, it is an effort to establish a balanced, effective, public-private collaboration among

organizations and individuals in all sectors of the health community.

#### Vision and Attributes

At their meeting in June 2007, the AHIC approved a set of principles to guide the work of defining and implementing the AHIC successor. Between April and June of 2007, ONC requested and received input<sup>3</sup> from three organizations on potential business models and an organizational design for an AHIC successor. Between June and July of 2007, ONC reviewed the input and, working with an industry subject

#### Design Guiding Principles

- The entity should exist for the purpose of individual/consumer benefit.
- The entity should establish and enhance trust among stakeholders.
- The entity should have broad participation across the health care industry stakeholders.
- The governing bodies of the entity should have necessary authority to make decisions, but only the authority that is necessary to do this.
- The entity should be feasible to establish and operate, and sustainable into the future.
- The entity should be adaptable over time and across future circumstances.

matter expert, consolidated the recommendations from the three proposals. This process led to the development of the vision and key attributes of the AHIC successor that are presented in this white paper.

The AHIC successor will be designed, established, and ready for operation by Spring 2008. The process and schedule for designing and establishing the new entity is described in later sections of this white paper.

#### A. Purpose and Scope

The AHIC successor will be an independent and sustainable public-private partnership bringing together the best of the public and private sectors into a trusted, decisive, effective organization for the creation and use of an interoperable nationwide health information system to improve and maintain the health and well-being of all individuals and communities in the United States.

The proposed scope of responsibility for the AHIC successor includes, but is not limited to, the following:

- Accelerate and coordinate current AHIC interoperability initiatives including standards harmonization and certification of health IT<sup>4</sup>
- Prioritize stakeholder requirements for nationwide health IT interoperability

<sup>&</sup>lt;sup>4</sup> The relationship between the AHIC successor, Health Information Technology Standards Panel (HITSP), and Certification Commission for Healthcare Information Technology (CCHIT) will be determined as the organization is designed.



<sup>&</sup>lt;sup>3</sup> Materials prepared by Alchemy LLC, Avalere Health LLC, and Booz Allen Hamilton, Inc. are available at <a href="http://www.hhs.gov/healthit/community/background/AHICsuccessor.html">http://www.hhs.gov/healthit/community/background/AHICsuccessor.html</a>.

<sup>4</sup> The relationship between the ALLO

- Advance the harmonization of technology standards and policies, including those to protect confidentiality, privacy, and security
- Oversee and facilitate the Nationwide Health Information Network (NHIN a networkof-networks), including necessary governance and/or accreditation of participant organizations
- Advance the certification of products, network participants, and/or operations

The key attributes, objectives, and/or considerations related to governance, business and operations, transition, and legal issues of the envisioned AHIC successor are presented in the following sections.

#### B. Governance Objectives

The following statements of objectives pertain to processes that determine how authority will be exercised, how members of the organization will be classified and represented, and how decisions will be made on issues of nationwide concern.

#### Membership

The AHIC successor should be open to membership by all individuals and
organizations in all sectors of the health community. The health community should be
organized into membership sectors that may be defined in any way the AHIC successor
chooses but must be inclusive of all relevant and affected parties in the health
community.

The concepts described in this white paper were refined using an illustrative prototype business model. Figure 1 presents the membership sectors that were identified as part of the AHIC successor prototype. These sectors were designed to support the creation of a governance body that includes all relevant stakeholders, and to inform decisions made by a governance body, such that no single sector controls or dominates the governance.

Sector Name	Sector Descriptions	
Ancillary Health Services	Those engaged in developing analysis, data or other tools relevant to health care, and those engaged in the retail dispensing of drugs and/or devices which legally require prescription (labs, pharmacies).	
Clinicians	Physicians or medical groups, nurses, or other providers licensed or certified by an appropriate authority.	
Consumers	Individuals who agree to seek medical or other health care from participating members.	
Employers/ Purchasers	Organizations that purchase/arrange for medical or other health care or assistance.	
Government	Representatives of Federal, State, City, Community, and Tribal government.	
Health Information Exchange	A multi-stakeholder entity that enables the movement of health-related data within state, regional, or non-jurisdictional participant groups.	
Institutional Providers	Hospitals, long term care facilities, home health agencies, clinics, and other facilities licensed or certified by an appropriate authority.	
Payers / Health Plans	Organizations providing/administering resources to sustain or improve health and well-being through payment of the costs of health care.	
Pharmaceuticals & Devices	Organizations engaged in the research, manufacture or wholesale distribution of drugs and/or devices which legally require prescriptions.	

Figure 1. Illustration of Membership Sectors and Definitions



2. The AHIC successor should have differing classes of membership with differing rights and obligations to provide for both *loosely*-bound and *tightly*-bound members.

Classes of membership are used in conjunction with membership sectors to provide as many pathways as possible for stakeholder participation. There will be situations when an organization will be a Direct Member of the AHIC successor, and situations where the same organization will be a Participating Member. For example, as illustrated in Figure 2, the Elm Street University System is a Direct Member representing the Institutional Provider Sector. The doctors, labs, pharmacies, and patients that comprise that system would be "loosely" bound to the AHIC successor through the Direct Members commitments. These Participating Members would not have separate voting rights or membership fees, and their obligations would be limited to the obligations of the member hospital system. Yet a Direct Member, such as the hospital system in this example, is not likely to always represent the exact interests of all of the affiliated participating members. Therefore, each of the Participating Members has multiple ways to directly connect to the successor organization. For example, the Main Street Physicians could also be a Direct Member through affiliation with the Clinician Sector. This complexity of membership mitigates the risk of any single sector dominating decisions that have nationwide impact. An illustration of member classes and their rights and obligations is presented in Figure 2.

Figure 2. Illustration of Membership Classes

- Main Street Physicians is a Direct Member in the Clinician Sector
- Elm Street University is a Direct Member in the Institutional Provider Sector
- Main Street Physicians is a part of Elm Street University and so they are also a Participating Member of the Institutional Provider Sector

## Illustrative Membership Classes

	Direct	Participating
Voting	Yes	No
Fees	Yes	No
Obligations / Rights	Always	Limited to formal relationship with Direct Member

- A **Direct Member** may be affiliated with multiple Participating Members
- Participating Members
   agree to participate and abide
   by AHIC successor standards
   through the Direct Member
- Only the Direct Member will have voting rights in the AHIC successor

#### **Governing Body**

- 3. The governing body (i.e., Board of Directors) should be selected by elective or appointive methods that result in a balanced representation of members in all sectors.
- 4. The structure of the AHIC successor should ensure that the views of all sectors will be adequately conveyed to any governing body and that its deliberations and decisions are neither dominated nor controlled by any single interest or sector.
- 5. Eligibility to be elected or appointed to the board should be clearly defined.



Figure 3 illustrates one method used to constitute a board that could represent all member sectors in a balanced manner. In this illustration, members self-select a membership sector and each sector's members play a role in filling a specific number of "seats" assigned to their sector.

Membership Sectors

Ancillary Health Services
Consumers
Clinicians
Employers/ Purchasers
Government/Public Health

Board of Directors

Board of Directors

Board of Directors

Board of Directors

Directors

Mealth Information Exchanges
Institutional Providers
Payers/Health Plans
Pharmaceuticals/ Devices

Board of Directors

Consumers

Board of Directors

Figure 3. Illustration of Membership Sectors and Board Composition

Members sectors elect x number of Board Members for their sector

Sector Name	No. Seats
Ancillary Health Services	х
Clinicians	х
Consumers	х
Employers/ Purchasers	х
Government/Public Health	х
Health Information Exchange	х
Institutional Providers	х
Payer/ Health Plans	х
Pharmaceuticals & Devices	х
At Large	х
AHIC Successor CEO	1

#### **Decision-Making Process**

- 6. AHIC successor bylaws should have clear delineation of voting rights, if any, of members and clear delineation between voting rights of members and the board.
- 7. Fiduciary duty of board members should be specified, whether to the constituency (sector) from which they were appointed or elected, or once appointed and elected, to the best interests of the whole of the AHIC successor.
- 8. Authority of the AHIC successor board as well as the rights and obligations of members should be clearly delineated. Specifically, the following should be delineated:
  - a. Authority of the board, if any, to set service fees or pricing of services to set service fees binding on members including limitations and methods to prevent abuse of such authority;
  - b. Authority of the board, if any, to adopt operating procedures and standards binding on members;
  - c. Authority of the board, if any, to adopt sanctions, fines, and/or penalties for violation of operating procedures;
  - d. Whether or not different classes of members should have different rights and obligations and, if so, whether they should be common within each class.
- 9. In order to ensure proper restraints on authority and protection of member rights and proper obligations of Members, the decision-making process of the AHIC successor should specify the use of quorums of board members, board voting procedures, and types of issues and decisions that require double majorities or super majorities of the board for adoption.



#### C. Business and Operating Objectives

The following statements of objectives pertain to protections, incorporation, financial considerations, and legal aspects of an operating business entity.

#### **Protections and Incorporation**

- 1. The AHIC successor should operate under a certificate of incorporation, detailed bylaws, and initial operating regulations and membership agreement(s) that reflect the most appropriate type of legal entity for the successor (e.g., for-profit, not-for-profit, stock, membership, partnership, government instrumentality).
- 2. Protection of the AHIC successor structure should be built into the certificate of incorporation and bylaws to prevent changes that would radically alter the structure and operations of the board or the protection of members who were relying on the structure as a condition of their membership.
- 3. The AHIC successor should identify and address all relevant attributes of business operations, including but not limited to, corporate law, best jurisdictions for incorporation or other legal formation, securities law, antitrust law, trademark and intellectual properties law, Federal and state law regarding membership by government entities and other legal issues affecting legal and successful operation.
- 4. The AHIC successor structure should allow for and encourage self-organization of members into health information exchange entities (HIEs) or other types of suborganization at any time, at any scale, for any reason consistent with AHIC successor policy and procedures without loss of the member rights and obligations of their constituent parts.

#### Management and Staffing

- 5. The AHIC successor operating structure could include, but not be limited to, (a) Chief Executive Officer; (b) Treasurer, CFO or equivalent for accounting, budgeting, financial control, capital formation to support automation at the clinical and institutional level, and all other similar or related activities; (c) Secretary and Counsel for legal advice and coordination of outside counsel, Board and Board committee minutes, evolution of bylaws and other corporate documents, voting lists and procedures, elections, and all similar or related activities; (d) Senior Membership Officer for membership and recruitment, publicity, advertising, marketing, public relations, and all other related activities; (e) Chief Operating Officer for personnel, internal operating matters, security, fraud, system operating procedures and all other related activities; (f) Senior Technology Officer for standards harmonization, certification, network services, and all other related activities; (g) Senior Data Uses Officer for data stewardship, privacy policy, accreditation, and uses of data for purposes such as public health, research, quality, and all other related activities.
- 6. The AHIC successor should establish standing or ad hoc advisory committees to bring the best possible expertise of members to bear on substantive matters in all areas of activity. The AHIC successor should identify methods whereby Management, under the direction of the board, can define the committees by establishing the charter,



appointing committee members, determining the functions, and coordinating the activities of new committees.

Figure 4 depicts the operating structure described in the preceding paragraphs.

- 7. The AHIC successor structure and operations should be, at a minimum, as innovative, decisive, and operationally efficient and effective as any private or public sector organization.
- 8. The structure and operations should be reliable and durable in purpose and principles of organization, yet malleable in form and function in order to evolve as rapidly as the technology it must use and the conditions in which it must operate.
- 9. The AHIC successor, to ensure its successful implementation, balanced governing structure and sustained operating success, should recruit a substantial portion of organizations in each sector of the health community, secure their membership agreement and accept

them as members in 2<sup>nd</sup> quarter 2008.

10. The AHIC successor should provide methods by which all organizations and individuals eligible to become members could be accommodated, if and when and if they voluntarily choose to become members, as well as multiple paths and choices for participating.

11. The AHIC successor should document a simple, non-punitive method by which members can

Membership CEO CFO Secretariat/Counsel COO Internal Technology Membership Data Uses Standing or Ad Hoc Advisory Committee Operating Level

Figure 4. Illustration of AHIC Successor Management and Staffing Structure

choose to leave the system should they decide the benefits do not substantially exceed the obligations of membership.

Revenue, Costs, Budgets and Capital

- 12. The AHIC successor should, no later than 1<sup>st</sup> guarter 2008, identify and obtain secure commitments for the necessary funding for operation throughout 2008 and 2009.
- 13. The AHIC successor should, by the middle of 2009, have developed methods and means to become financially and operationally sound and secure for the years 2010 through 2014.



#### D. AHIC to AHIC Successor Transition Objectives

The transition objectives will ensure an orderly hand-off from AHIC to the AHIC successor, and that the highly successful work of standards harmonization and adoption will be sustained. AHIC Workgroup activities will be ongoing until their charges are met in the months between now and 4<sup>th</sup> quarter 2008, and a future path has been charted. AHIC recommendations resulting from workgroup efforts are expected to continue and will be addressed by Secretary Leavitt.

The following statements of the AHIC successor objectives pertain to an initial operating period defined by the transition of leadership and priority-setting from the Federal Advisory Committee effort (i.e., AHIC) to the new, independent public-private partnership.

#### **General Transition**

- The AHIC successor should obtain a majority of eligible charter members from each sector who have applied for and met the criteria for membership, or at least a sufficient number to demonstrate that the AHIC successor will become a balanced, multistakeholder entity that includes all relevant and affected parties.
- The AHIC successor should document the anticipated accomplishments in each of its
  first three years of operation to clearly establish its credibility and enhance its ability to
  attract members, secure resources and increase the rate of accomplishment in
  subsequent years through 2014.

Continue and Accelerate Current AHIC Interoperability Initiatives (Initial Operations Stage)

- The AHIC successor should analyze current AHIC initiatives and functions to determine the best method and means to assume responsibility for interoperability initiatives between March 31, 2008 and October 31, 2008, the initial AHIC successor operations stage.
- 4. The AHIC successor should be structured, staffed, and operated so that assumption of revenue streams and/or direction of present AHIC activities will not only be effectively transferred and continued, but also improved and accelerated.

#### **Identify and Address Obstacles**

- 5. Upon successful transition of AHIC responsibilities related to the advancement of the harmonization and adoption of standards and acceleration of efforts to achieve interoperability, the AHIC successor should identify existing obstacles to the emergence of an effective interoperable nationwide health information system, including but not limited to:
  - Limited technical capacity for harmonization and specification of standards
  - Disincentives
  - Legislative or regulatory impediments
  - Conflicting state and Federal laws or regulations
  - Availability of capital needed by members for implementation and adoption of electronic health information systems
  - Absence of critical infrastructure needed to connect members.



- 6. The AHIC successor should prioritize identified obstacles in order of importance, and identify means and methods to overcome each.
- 7. The AHIC successor should identify the time and resources required to remove each obstacle, and demonstrate how the AHIC successor would be effective in obtaining resources and removing obstacles.
- 8. The AHIC successor should document which obstacles the AHIC successor could remove in each of its first three years of operation that would clearly establish its credibility and increase the rate of accomplishments in subsequent years through 2014.

#### **Identify and Realize Opportunities**

- 9. Based upon a sound policy framework to ensure confidentiality, privacy, and security, the AHIC successor should identify opportunities to create and use interoperable health information for informing direct clinical care and for purposes in addition to informing direct clinical care. These uses of health information may include but are not limited to: clinical care, biosurveillance, mobilization of clinical and related response to emergencies, post-market surveillance of medical products, clinical research including clinical trials for medical products, tracking of fraud and abuse in health care, remote delivery of clinical care, population and health services research, measurement and reporting of provider performance, and personal health management.
- 10. The AHIC successor should prioritize opportunities in order of importance, and identify means and methods to realize each.
- 11. The AHIC successor should identify the time and resources required to realize each opportunity and demonstrate how the AHIC successor could be effective in obtaining resources and realizing the opportunities.

#### E. Legal Considerations

In order to successfully implement the vision described in this paper, the AHIC successor will need to consider organizational issues which have legal implications in three primary areas: the successor organization's status and structure, anti-trust, and government participation.

#### **Organizational Issues**

In the planning and design phase, options relating to formation, tax status, governance structure, and relationships with participating organizations and individuals will need to be considered in establishing a successor organization.

#### 1. Formation

The entity's form and tax status will be determined as the organization is being designed in accordance with the well worn adage that "form follows function." There could be reason to consider forming the AHIC successor as a non-profit (non-stock) membership corporation. Some of the factors related to this consideration are:

- the principal purpose of the public-private partnership;
- governance rules are more established for a corporate entity than they are for an unincorporated association or partnership;



- membership (non-stock) corporations are a recognized form that afford an
  opportunity for participation to a broad array of participants, yet flexible enough to
  enable the structuring of a governing body, once elected, that is empowered to
  make timely decisions;
- the members are not likely to invest funds in the AHIC successor for purposes of a direct financial return (so that non-profit status should not adversely affect access to capital); and
- some of the early funding may need to come from foundations and others who will be required to make initial funding available to a non-profit.

#### 2. Membership

The membership would consist of those organizations, entities and persons who want a voice in the running of the AHIC successor and a vote in its affairs (including the election of its governing board), who would become members of an applicable stakeholder sector and agree to pay dues and make initial capital contributions (members). All members in all categories would be expected to sign Participation Agreements that bind them to using the AHIC successor's standards, policies, and procedures when transacting business with the AHIC successor or another member of the AHIC successor. In order to induce broad and robust membership in the AHIC successor, any member would have the right to withdraw from the AHIC successor at any time in its discretion, on designated written notice, without adverse economic consequences to that member.

#### Board

The AHIC successor would be governed by a board consisting of high-level representatives of the multiple stakeholder interests, preferably senior executives with experience in running organizations, developing innovative new models, and participating in board-level activities. Directors would be expected to serve in both representative and fiduciary roles – with responsibilities to consult with their sector constituencies and, at the same time, expected to make determinations in the course of Board deliberations in what they determine to be in the best interests of the AHIC successor, and the broad public and stakeholder interests to be served.

#### 4. The Timetable

Not later than the Spring of 2008, the AHIC successor, with its governing documents, will need to be formed/documented after vetting with a broad array of stakeholder sectors and interest groups, together with an in-place budget, a sustainable business plan, and actual realizable funding commitments that assure the financial and operational viability.

#### **Antitrust Issues**

Many of the AHIC successor's members will be competitors or potential competitors. This means that competitors will be collaborating in numerous ways. Such collaborations raise the possibility of violations of the antitrust laws by the AHIC successor and/or some of its members. However, given the pro-competitive benefits of an interoperable nationwide health information system and assuming that the AHIC successor is structured carefully and correctly, the federal antitrust laws should not be a problem for the AHIC successor.



Antitrust law would likely treat the AHIC successor as a joint venture. Integrated joint ventures which promise pro-competitive benefits such as the AHIC successor are evaluated under the rule of reason. Rule of reason analysis focuses on the state of competition with, as compared to without, the relevant agreement. The central question is whether the joint venture is more likely to benefit or harm competition. In an efficiency-enhancing joint venture, participants collaborate to perform one or more business functions, such as research and development or production, and thereby benefit consumers by reducing price or enhancing quality, service, or innovation. Typically such a joint venture combines technology or other complementary assets to achieve procompetitive benefits that the participants could not achieve separately. Such is the situation here. The AHIC successor is intended to create a unified platform to accomplish a task – creation of an interoperable nationwide health information system – that no single entity could coordinate on its own.

#### **Government Participation**

The Federal Government does not intend to establish the AHIC successor, nor does it anticipate that the functions of the AHIC successor include any that are inherently governmental. The Federal government though does intend to participate in the anticipated activities of the AHIC successor, such as those pertaining to voluntary consensus standards, consistent with its statutory authority. In fact, the National Technology Transfer and Advancement Act of 1995 (NTTAA) is relevant to the proposed purpose and actions of the AHIC successor by providing that all Federal agencies and departments shall use, unless inconsistent with applicable law or impractical, data and technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments. The Office of Management and Budget (through OMB Circular A-119, as amended) has defined voluntary consensus standards bodies as domestic or international organizations which plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures. Further, they have the following attributes:

- Openness
- 2. Balance of interest
- 3. Due process
- 4. An appeals process, and
- 5. A Consensus process

To increase the likelihood that the standards named or recognized will meet both public and private sector needs, both the NTTAA and the Circular encourage the participation of federal representatives in these bodies, to the extent it is compatible with the agency's mission and authorities and in the public interest. In the planning stages of the AHIC successor and as governing documents are developed, these attributes can be considered in consultation with the Federal Government to ensure the compliance with the OMB definition of a voluntary consensus standards organization.

There are a number of existing public-private partnerships that involve the participation of the Federal Government as a member of a non-governmental organization and the service of government employees as board members. In some cases, government employees



play a formal role in governance as representatives of government agencies; in other cases, they serve as board members on a more informal basis. Examples of such organizations include the National Quality Forum, the American National Standards Institute, and the North American Energy Standards Board. Please refer to Appendix A for more information.

Federal employees participating in the AHIC successor would remain subject to the applicable ethics laws, including those pertaining to conflict of interests and appearance of partiality, as they would be taking such actions in their official capacity as Federal employees. Federal employees who participate with the AHIC successor as board members may have certain fiduciary obligations to the successor organization. This may give rise to certain conflict of interest issues with respect to their actions as Federal officials. These employees should consult with their agency ethics officials prior to participating in such actions.

### Value Proposition

Historically, there has been a competitive and growing market for health IT. There is a market emerging, to a lesser degree, for regional and specialty HIEs. The dynamics and forces at work in these markets are producing health information network elements but are not yet converging into an interoperable nationwide network-of-networks on their own. These regional and specialty markets need a catalyst to leverage existing economic market influences. The President's call for most Americans to have access to electronic health records (EHRs) by 2014 and the formation of the AHIC and the Office of the National Coordinator for Health IT have acted as this catalyst. As a result, through June 2007, several major milestones have been achieved. Specifically, the HHS Secretary is poised to recognize 30 interoperability standards and detailed implementation guidance that have been harmonized through the work of the Health Information Technology Standards Panel (HITSP), and he has recognized the Certification Commission for Healthcare Information Technology (CCHIT). Subsequently, CCHIT has certified over 80 ambulatory EHR products, which can now be donated to health care providers as specified in final regulations that create a Stark exception and an anti-kickback safe harbor. This progress clearly demonstrates the value of a focused set of nationwide priorities and provides the incentive to take the AHIC process to the next level and refine priorities and accelerate actions. Moreover, the successor entity will have the full support of the Secretary of HHS and the necessary participation of government executives and experts.

In addition, future progress will be supported through the broad reach of Federal procurement. As specified in *Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs* on August 22, 2006, recognized interoperability standards will be required for use by each agency that implements, acquires, or upgrades health information technology systems used for the direct exchange of health information between agencies and with non-Federal entities. Similarly, each agency will require compliance with interoperability standards in contracts or agreements with health care providers, health plans, or health insurance issuers such that as each provider, plan, or issuer implements, acquires, or upgrades health information technology systems, it shall utilize, where available, health information technology systems and products that meet recognized interoperability standards.



Through the AHIC successor, all organizations in the health community will have an unprecedented opportunity to continue the role of community leader and change agent that was initiated by the Secretary of HHS. Through the AHIC successor, organizations from across the health care community will have a direct opportunity to set priorities for the nation as part of balanced public-private collaboration. With the expanded role of the private sector and its best practices, the AHIC successor can accelerate decisions on health IT. With the continued strong participation of the public sector, the AHIC successor will have a high likelihood of successfully securing government actions to adopt these same standards. The AHIC successor can ensure alignment of certification criteria with nationwide priorities to achieve interoperability, and accelerate adoption of best practices and policies to ensure privacy and security.

To be successful, the AHIC successor must overcome a significant barrier: how to demonstrate the value that could accrue from interoperability and the sharing of information across EHRs, HIEs, and the NHIN. Most stakeholders have preconceived notions about the value of health IT, and many views are based on anecdotal evidence. Studies exist on the return on investment of health IT, but most are narrow in scope and focused on the providers of care. Demonstrating that value can be created and captured more broadly across stakeholder groups is critical to widespread adoption and use. Based on anecdotal evidence and expert opinion, the nature and level of benefits that can be achieved with a fully interoperable nationwide health information system will vary across health care sectors, as illustrated in the following figure.

Figure 5. Value Proposition Across the Health Care Community Sectors

#### Stakeholders Value Proposition Advanced interoperability between EHRs, NHIN, and specialty networks specific to ancillary services **Ancillary Health** (e.g., labs, radiology and pharmacy) Services • Decreased operating costs due to automated interactions directly with providers Interoperable health IT (Clinical Decision Tools) that allow them to deliver the highest quality health care to their patients Unprecedented opportunity to participate in priority setting, ensuring that priorities are informed by Clinicians clinically relevant expertise and advance the level and quality of patient care Mitigation of risks to clinicians associated with liability, privacy, and security stemming through advancement of the appropriate exchange of data Recipient of markedly improved quality, safety, efficiency, and convenience of health care; dramatically increased continuity of care across their care providers Increased ability to manage their health and well-being Consumers Defined and influential role in advancing interoperability of health IT • Increased role in the development of privacy and security policies and practices Robust, comprehensive, and interoperable Personal Health Record • More efficient, higher quality, lower cost care for their employees resulting in significant reductions in the rate of increase in health care premiums • Increased participation in setting unified nationwide health IT priorities **Employers** and Improved ability to manage constituents' health and associated costs through incentives for preventative Other treatment of chronic conditions **Purchasers** • Healthier employees and their families will result in less sick days and use of family leave for health related issues, thereby improving employee productivity More efficient, higher quality, lower cost care for their employees and beneficiaries resulting in significant Government

reductions in the rate of increase in health care costs paid for with public funds



**Agencies** 

#### Stakeholders

#### Value Proposition

Health Information

Exchanges

- Vastly improved Public Health information systems, with highly effective surveillance and emergency response capabilities resulting in healthier populations and communities
- Reduced entitlement costs due to fraud detection (CMS)
- Increased voice in nationwide decision-making
   Increased ability to share aggregated data for one
- Increased ability to share aggregated data for quality measurement and reporting, which is an element of sustainable business models for HIEs
- Development of a competitive marketplace for HIE technology and services
- Institutional Providers
- Health IT solutions that allow them to deliver the highest quality health care to their patients
- Improve ability to measure and manage provider performance through certified EHRs and HIE
- Accelerated development of interoperable network services to share data across care settings to improve continuity and quality of care
- Payers/ Health Plans
- More efficient, higher quality, lower cost care for their beneficiaries
- Improved ability to measure and manage provider performance
- Ability to facilitate disease management and provide other value-added services
- Pharmaceuticals/ Devices
- Reduced cost for research due to rapid access to standardized, interoperable data in clinical trials
- Potential to automate enrollment of patients in clinical trials from EHRs and/or PHRs
- Potential to expedite development of targeted therapies
- Enhanced post-marketing surveillance and risk management of marketed products

From a cross-sector perspective, the AHIC successor will provide a forum outside of Government, but with the active participation and input of Government, that allows members to build on progress made and expand the priorities to align with market demand and at the same time to improve the health and well-being of individuals and communities. As an independent public-private partnership, the AHIC successor can move swiftly to make decisions (not just recommendations) and with public sector input, the decisions that are acted upon can have a significant market impact. Consequently, the AHIC successor can act as a guarantor of the efficiency and integrity of an interoperable nationwide health information system, mitigating risk to adopters of health IT.

The AHIC successor must recognize that there are different perspectives on the value of health IT and acknowledge the constructive tensions that exist among different sectors. Although an interoperable nationwide health information system should bring substantial benefits to all sectors, no member of the AHIC successor can expect that on every occasion, decisions that need to be made will be beneficial to every sector. The problems of the health care system simply cannot be addressed without some effort and temporary sacrifices for the common good. For example, if approximately 20% of lab tests are needlessly repeated due to lack of interoperable, transportable information, then loss of volume due to reducing redundancy will have a negative impact on the revenue of laboratories and providers. In addition, in the institutional provider and clinician sectors there is a questionable business return on the investment associated with adopting technology to enable interoperability in certain circumstances.

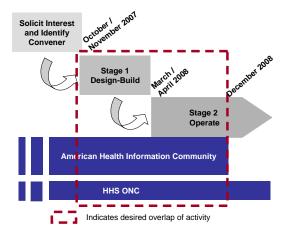
To be credible, the AHIC successor must fully appreciate and openly acknowledge that member rights cannot be ensured without obligations, and that the public good associated with interoperable health information cannot be obtained without effort and sacrifice.



# **AHIC Successor Implementation Strategy**

For the purposes of facilitating the establishment of the AHIC successor and convening a planning board, HHS will award a Cooperative Agreement that allows for substantial involvement by the Federal Government. HHS will solicit interest through public comment on this white paper and through a public meeting on August 16, 2007. HHS will then select a grantee that includes or will convene representatives from the private and public sectors to design and establish the AHIC successor. HHS and other Federal Agencies and Departments will participate in the

Figure 6. AHIC Successor Implementation Strategy



design process and fully leverage the prior and on-going work of HHS and AHIC. The public input received from this white paper will also inform this process. Once a new legal entity is established and after certain conditions are met, HHS will support that entity through additional funding that will enable initial operations and transition of specific AHIC responsibilities by Fall 2008.



### **APPFNDIX A**

The following organizations are relevant models for the Federal Government's participation as a member of the AHIC successor and the service of Government employees as AHIC successor board directors.

- National Quality Forum (NQF). NQF is a not-for-profit membership organization created to develop and implement a national strategy for health care quality measurement and reporting. Established in response to a formal recommendation from the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry in 1998, it has broad participation from all parts of the health care system, including government. Its functions include endorsing voluntary consensus standards and it explicitly relies on the NTTAA in performing its functions relative to government. See McLean, The Implications of Patient Safety Research & Risk Managed Care, 26 S.III.U. L.J. 227, 241-2 (Winter 2002). Its Board includes the Administrator of the Centers for Medicare and Medicaid Services, the Director of the Agency for Healthcare Research and Quality, and the Under Secretary for Health in the Veterans Health Administration.
- American National Standards Institute (ANSI). ANSI oversees the creation, promulgation, and use of thousands of norms and guidelines across nearly all business sectors. Founded in 1918 by five engineering societies and three government agencies. it is a private, nonprofit membership organization "supported by a diverse constituency of private and public sector organizations." Its Board includes the Standards Executive for the Environmental Protection Agency.
- North American Energy Standards Board (NAESB). NAESB serves as an industry forum for the development and promotion of standards that will lead to a seamless marketplace for wholesale and retail natural gas and electricity. It was created as a result of an order of the Federal Energy Regulatory Commission (FERC) in 1992. There are no Federal Government employees on the Board at this time, although the Board does include state government representation.



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